## (19) World Intellectual Property Organization

International Bureau





(43) International Publication Date 8 January 2004 (08.01.2004)

PCT

## (10) International Publication Number WO 2004/002404 A3

(51) International Patent Classification<sup>7</sup>: C07K 17/00

A61K 38/21,

(21) International Application Number:

PCT/US2003/019261

(22) International Filing Date: 18 June 2003 (18.06.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/393,066 28 June 2002 (28.06.2002)

- (71) Applicant: NASTECH PHARMACEUTICAL COM-PANY INC. [—/US]; 3450 Monte Villa Parkway, Bothell, WA 98021-8906 (US).
- (72) Inventors: QUAY, Steven, C.; 23632 Hwy 99 Ste. FPMB 454, Edmonds, WA 98026-9224 (US). GUPTA, Malini; 1 Carmen Court, Dix Hills, NY 11746 (US). DE MEIRE-LES, Jorge, C.; 33 Renee Road, Syosset, NY 11791 (US). ABD EL-SHAFY, Mohammed; 428 Town Line Road, Hauppauge, NY 11788 (US).
- (74) Agent: LUNN, Paul, G.; Nastech Pharmaceutical Company Inc., 3450 Monte Villa Parkway, Bothell, WA 98021-8906 (US).

- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

## Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
- (88) Date of publication of the international search report: 17 June 2004

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: COMPOSITIONS AND METHOD FOR ENHANCED MUCOSAL DELIVERY OF INTERFERON BETA

(57) Abstract: Compositions and methods are provided for intranasal delivery of interferon-β yielding improved pharmacokinetic and pharmacodynamic results. In certain aspects of the invention, the interferon-β is delivered to the intranasal mucosa along with one or more intranasal delivery-enhancing agent(s) to yield substantially increased absorption and/or bioavailability of the interferon- $\beta$ and/or a substantially decreased time to maximal concentration of interferon- $\beta$  in a tissue of a subject as compared to controls where the interferon- $\beta$  is administered to the same intranasal site alone or formulated according to previously disclosed reports. The enhancement of intranasal delivery of interferon-B according to the methods and compositions of the present invention allows for the effective pharmaceutical use of these agents to treat a variety of diseases and conditions in mammalian subjects.

## INTERNATIONAL SEARCH REPORT

International application No.

			PC17US03/19261		- 1
A. CLA	SSIFICATION OF SUBJECT MATTER				7
IPC(7) US CL	: A61K 38/21; C07K 17/00 : 424/85.6; 530/351				
	o International Patent Classification (IPC) or to both	national classification	and IPC		
B. FIEL	DS SEARCHED	Introjuu viassiiivatioii	and if C		-
Minimum do	ocumentation searched (classification system followed	d by classification sym	bols)		7
U.S.: 4	24/85.6; 530/351				- }
Documentati	on searched other than minimum documentation to the	ne extent that such doc	uments are include	d in the fields searched	7
					1
					ı
Electronic de	ata base consulted during the international search (na	me of data has and u	thana maastiashla	roansh tanna was d	7
STN, EAST:	; search terms: interferon beta, mucosal, intranasal,	steroid	vnere practicable, s	search terms used)	
C. DOC	UMENTS CONSIDERED TO BE RELEVANT				$\dashv$
Category *	Citation of document, with indication, where appropriate, of the relevant passages			Relevant to claim No.	$\dashv$
X, P	US 6,465,425 B1 (TRACY et al.) 15 October 2002 (15.10.2002), column 5, lines 20-51			1-24, 33-91	$\dashv$
	and 60-67, column 6, lines 1-10, and column 10, lines 60-69.		,		
Y				30,31	
Y	US 5,906,816 (SOOS et al.) 25 May 1999 (25.05.	1999) column 3 lines	40-50	30,31	
•	25 5,700,810 (5005 ct at.) 25 Way 1999 (25.05.	1999), column 3, inics	40-50	30,31	
				Į	ı
					1
					1
					1
				•	
					1
				L	1
Further	r documents are listed in the continuation of Box C.	See patent	family annex.		
	special categories of cited documents:			ternational filing date or	-
		priority date	and not in conflict with	the application but cited to	
	t defining the general state of the art which is not considered to ticular relevance	understand th	e principle or theory ur	derlying the invention	
-				e claimed invention cannot be	1
date	oplication or patent published on or after the international filing		e document is taken alor	dered to involve an invertive	
"L" documen	t which may throw doubts on priority claim(s) or which is cited	"Y" document of	particular relevance: the	e claimed invention camot be	
to establish the publication date of another citation or other special reason		considered to	involve an inventive st	tep when the documen/is	
(as specif	nea)		th one or more other suc being obvious to a perso		İ
"O" document	t referring to an oral disclosure, use, exhibition or other means		mber of the same patent	į,	
	t published prior to the international filing date but later than the	o. document me	o. o. the same patent	j'	
	date claimed actual completion of the international search	Date of mailing of th	e international sea	rch report	1
	•		10 ADD	2001	
12 January 2004 (12.01.2004) Name and mailing address of the ISA/US		Authorized officer			
	atting address of the ISA/US il Stop PCT, Attn: ISA/US	Authorized officer			
Cor	mmissioner for Patents	Janet Andres	NYIIA	VII Vin L A	
	D. Box 1450 xandria, Virginia 22313-1450	Telephone No. 702	308-0196	1/ 2010	1
	o. (703)305-3230	'		-	
	A/210 (second sheet) (July 1998)			<del></del>	